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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,571

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Susan J. Drapeau

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9546

7590

10/17/2007

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,571	DRAPEAU ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-7, 11, 12, 20, 26-28, 50, 52, 53, 56, 57, 59, 60 and 62-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 50, 52, 53, 56, 57, 66-72, 75, 76 and 89 is/are allowed.
- 6) ☒ Claim(s) 3-6, 11, 12, 20, 26-28, 59, 60, 63-65, 79, 80 and 83-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the paper filed on 08/03/2007.

The amendments to the claims are acknowledged.

Status of the Claims

Claims 3-7, 11, 12, 20, 26-28, 50, 52, 53, 56, 57, 59, 60, 62-89 are pending and under consideration. The amendments to the claims are acknowledged.

New claims 67-89 were introduced.

New Rejections necessitated by the amendments the claims

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59, 60, 62, 63, 64, 79, 80, and 83-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 60 and 62 introduce new matter where the composition is sterile. If to the contrary, Applicants are required to specifically point out in the specification where the support for "sterile" is present.

All dependent claims are included in this rejection because they depend from rejected independent claims 60 and 62.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59, 60, 62-64, 79, 80, 83-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Bianchi, U.S. 2001/0018614 in view of Hendricks et al. U.S. 6,117,979.

Bianchi teaches an implant for the repair of bone defects, see Abstract.

Where the osteogenic implant is crosslinked, see [0032], and where collagen is crosslinked with carbodiimide or its derivatives, see [0078]; (See instant claims 3, 4 and 60; the crosslink with carbodiimide will form an amide linkage). The implant is porous, see [0054, 0056], and where the implant is a collagen sponge [0043]; (See instant claim 4; the sponge maintain its capacity to maintain its shape when hydrated and regain its height following compression when hydrated). The implant contains growth factors, see [0043]; (instant claims 5, 26, 27, 28, 59, 80; the additives, such as growth factors can be bound to collagen or DBM and where the crosslinkage is not complete the additives may not be completely bound to collagen or DBM). Where the demineralized bone matrix is present about 15-33 weight %, see [0044]; (instant claims 6, 60).

Claims 11, 12, 60, 63 are included in this rejection because DBM comprises collagen and is therefore dispersed in collagen, where the collagen is a scaffold protein and the particle size of DBM is an inherent property produced by the method of forming the instant composition.

Bianchi does not teach crosslink in presence of NHS and acidic conditions.

Hendricks et al. teach implants that are crosslinked with carbodiimide in the presence of NHS or EDC, where such crosslinking provides collagen material with a high degree of crosslinking. See column 3, lines 13-31. (See instant claims 3 and 4).

Also, in column 10, lines 34-42, the crosslinking with NHS for example, is performed in acid conditions in the presence of propionic acid. (See instant claims 20 and 79).

Boyce et al. (U.S. 2001/0043940 A1) state that the bone particles can be combined with one or more biocompatible components, such as plasticizers [0054]; where suitable plasticizers include liquid polyhydroxy compounds as glycerol, or monoacetin etc. See [0060]. (See instant claims 60, 64, 65)

Therefore, it would have been obvious to a person having ordinary skill in the art to make a composition comprising crosslinked DBM and collagen as taught by Bianchi et al. and to crosslink the collagen in the presence of NHS in acidic conditions as taught by Hendricks et al. and to add a plasticizer as taught by Boyce et al. because such compositions are known in the prior art and the slight variations in the choice of the known crosslinking agents and the percent of crosslinkage that will determine the

particles sizes and the form, in which such compositions are administered to a patient, as in a paste form, for example, are known in the art and thus the invention is obvious.

Conclusion

Allowable claims: Claim 7 (and dependent claims: 67-72, 89) and claim 52 (and dependent claims: 50, 53, 56, 57, 66, 75, 76) are allowable. It appears that the allowable subject matter refers to osteoinductive composition having 55 to 85 wt% based on combined weight of DBM and collagen protein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-273-0931. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER